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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/843,295      | 04/25/2001  | Noel Caplice         | 07039-175001        | 7824             |

7590 07/01/2002  
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EXAMINER

NAFF, DAVID M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/843295

Applicant(s)

Caplice et al

Examiner

N. Hoff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/25/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-39 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-39 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Claims in the application are 1-39.

Restriction to one of the following inventions is required under 35  
U.S.C. 121:

I. Claims 1-37, drawn to an implantable medical device that may  
5 contain cells for producing a polypeptide, classified in class  
435, subclass 176.

II. Claims 38 and 39, drawn to a method of delivering a polypeptide  
to a mammal by implanting the implantable medical device  
containing cells that produce the polypeptide, classified in  
10 class 424, subclass 93.7.

The inventions are distinct, each from the other because:

Inventions I and II are related as process and apparatus for its  
practice. The inventions are distinct if it can be shown that either:  
(1) the process as claimed can be practiced by another materially  
15 different apparatus or by hand, or (2) the apparatus as claimed can be  
used to practice another and materially different process. (MPEP §  
806.05(e)). In this case the apparatus (implantable medical device) can  
be used to practice a materially different process. For example, the  
apparatus can be used *in vitro* to produce a polypeptide such an enzyme  
20 that can be used *in vitro* to produce a reaction product. Furthermore,  
the apparatus can be used *in vitro* to produce a cell growth polypeptide  
that can be used for promoting cell growth during culturing *in vitro*.

Because these inventions are distinct for the reasons given above  
and have acquired a separate status in the art as shown by their

different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even  
5 though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application.  
10 Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on  
15 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the  
20 examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.


Application Number: 09/843,295  
Art Unit: 1651

Page 4

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

5

DMN  
6/27/02

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT ~~1651~~ 51